

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND : NO.: 1:13-md-02419(FDS)
COMPUNDING PHARMACY, INC.
PRODUCTS LIABILITY LITIGATION : July 3, 2013

**MEMORANDUM IN SUPPORT OF
MOTION TO QUASH AND TO MODIFY**

PRELIMINARY STATEMENT AND BACKGROUND

This case arises from contaminated pharmaceutical preparations compounded and distributed by, or under the auspices of, New England Compounding Pharmacy (“NECP”) and/or a related entity known as Ameridose, LLC (“Ameridose”). The movant, non-party, Liberty Industries, Inc. (“Liberty”), a company located in East Berlin, Connecticut, was hired to design and construct, in accordance with clean room standards specified by NECP and/or Ameridose, what are known as “clean rooms” to be used for the NECP and Ameridose processes.

Beginning in 2005, Liberty designed and installed three (3) different projects for NECP or Ameridose. The clean rooms worked on by Liberty were designed and constructed in accordance with the International Organization for Standardization (“ISO”) standards or Federal Standard 209E as requested by NECP and/or Ameridose. Upon completion, all clean rooms were certified by an independent testing laboratory as compliant with the requested

standards. Liberty had no involvement in ongoing maintenance, repair, service or ongoing use of the clean rooms it designed and installed. Affidavit, Robert Kaiser (“Kaiser Aff.”), attached as Exhibit A, ¶¶ 2-7.

Pursuant to Fed. R. Civ. Proc. 45, on June 21, 2013, the Plaintiffs’ Steering Committee (“PSC”) in this matter, through counsel, served upon Liberty a subpoena to testify at a deposition. The subpoena included 35 requests for the production of documents. A copy of the subpoena is attached as Exhibit B.

Liberty has gathered all documents relating to the three projects. These have been made available for inspection and copying by the issuing party. The identified documents are in binders and various cardboard boxes and consist of approximately 5000 pages. In addition, approximately 250 D-size engineering drawings must be copied. The cost of copying is quoted at approximately \$2900.00. Over 230 photos of Room 19822/10 and Room 23875/10 taken by Liberty during construction have been identified. Photos of Room 35259/10 cannot be located. Finally, over 1300 emails are to be transferred to a pst--file. Kaiser Aff., ¶¶ 8-9.

Liberty employs 23 people. Of those, only 3 are engineers with the technical expertise required to review and identify documents containing commercially confidential information or trade secrets maintained by Liberty which does business in the competitive clean room industry. It is estimated that this task will require at least 100 hours on the part of these individuals and necessarily will entail that they will be unavailable for other revenue generating work because they are pouring over reams of documents. Alternatively, Liberty’s sole

administrative assistant will have to devote approximately 40-50 hours to stamping every single document as confidential and produced pursuant to a protective order.¹ To date, Liberty has incurred over \$5000 in legal fees, including the costs associated with preparation of this motion. Id., ¶¶ 10-12.

Citing “an eye towards minimizing costs to [their] client, the parties, and the Court” the issuing attorneys have declined to bear the cost of copying. Instead, the representation is that reimbursement of a portion of Liberty’s costs “may” be reimbursed. The PSC also declined the opportunity to inspect to identify relevant documents and apparently wishes to have copies of everything gathered by Liberty to this point. Email from Attorney Jennifer Frushsour, June 26, 2013, attached as Exhibit C.

In view of Liberty’s limited resources and the burden and expense associated with compliance, in accordance with Fed. R. Civ. Proc. 45(c) (3), Liberty objects and moves that the subpoena be quashed. Alternatively, Liberty seeks an order that the costs associated with compliance be shouldered by the PSC.

LAW AND ARGUMENT

I. The Subpoena Served Upon Liberty Will Subject It To An Undue Burden.

“On timely motion, the issuing court must quash or modify a subpoena that: ...subjects a person to undue burden.” Fed. R. Civ. Proc. 45(c)(3). It is established in this Circuit that

¹ Attorney Marc Lipton, who issued the subpoena on behalf of the PSC, has indicated that a protective order shortly will be entered into with respect to NECC documents, so a comparable protective order as to

“concern for the unwanted burden thrust upon non-parties is a factor entitled to special weight in evaluating the balance of competing needs.” Behrend v. Comcast Corp., 248 F.R.D. 85, 85 (D. Mass. 2008) (quoting Cusumano v. Microsoft Corp., 162 F. 3d 708, 717 (1st Cir. 1988)). Additionally, “[a] party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena.” Fed. R. Civ. Proc. 45 (c)(1).

The determination of whether a subpoena *duces tecum* presents an undue burden, involves consideration of factors such as “the relevance of the documents sought, the necessity of the documents sought, the breadth of the request … expense and inconvenience.” Behrend, at 86 (quoting Demers v. LaMontagne, Civ. No.A-98-10762-REK, 1999 WL 16278, at *2 (D. Mass. May 5, 1999)). “Usually, absent an order compelling document production, a non-party bears the cost of production.” Behrend, at 86. Depending upon the equities of a particular case, however, costs may be reallocated. Id. This cost allocation entails consideration of: 1) whether the non-party actually has an interest in the outcome of the case, 2) whether the non-party can more readily bear the costs than the requesting party, and 3) whether the litigation is of public importance.” Id. (citing In re Exxon Valdez, 142 F.R.D. 380, 383 (D.D.C. 1992).

Liberty’s last project for NECP/Ameridose was completed and certified in March, 2008. Liberty had no further involvement with those entities and has no interest in this litigation. Indeed, the design and construction of areas that started out as clean rooms suitable for the

Liberty’s documents is acceptable.

NECP/Ameridose operations 4-7 years ago, but ended up as contaminated, is of little relevance to this litigation. This is particularly so because, while Liberty designed the clean rooms to meet the design criteria as specified by NECP/Ameridose, the scope of the work consisted of just installation of clean room walls, ceilings, lights and ceiling mounted HEPA filters. The flooring, electrical work and the HVAC air handling system required to remove contaminating particulates were designed and installed by other contractors selected by NECP/Ameridose.

Kaiser Aff., ¶ 13.

Despite the PSC's cost saving concerns, the court docket report in this case reflects that at least seventeen (17) different law firms have entered appearances on behalf of the many plaintiffs. The expenses associated with Liberty's compliance can be divided among all the firms which may eventually access the online repository to be created by the PSC. To require that Liberty absorb the costs of compliance by merely copying everything related to NECP/Ameridose and turning it over in a format acceptable to the PSC, when one or more of these plaintiff firms could designate individuals to inspect and identify documents, is manifestly inequitable.

Finally, while this litigation undoubtedly is of importance to the individual plaintiffs, the NECP/Ameridose operations have been forced to shut down as a result of the circumstances giving rise to this action. The importance to the public at large is therefore limited.

For all of these reasons, the subpoena at issue should be quashed. Alternatively, Liberty requests that this Court order that all of the costs associated with Liberty's compliance be borne by the PSC.

I. Several Of The PSC Production Requests Are Objectionable.

The subpoena served upon Liberty also includes production requests to which Liberty objects on various grounds. In the event that Liberty does in fact comply with the subpoena, it specifically preserves the following objections.

11. Written standards, instructions, and specifications related to the processes, methods, policies, and/or protocols used by Liberty to design, construct, install, maintain, and/or repair any NECP cleanroom.

OBJECTION: This request is overly broad and unduly burdensome. Inasmuch as the clean rooms were designed by professional engineers utilizing years of education, professional training and experience, this request implicates a wide range of not readily identifiable materials. Additionally, Liberty's methodology, practices and policies have been developed and accumulated over the course of all its years of operation. For all of these reasons, this request is incapable of meaningful response.

13. All documents related to inspections, citations, violations, and/or notices of lack of compliance from Federal, State and/or Local agencies related to any cleanroom designed, constructed installed, maintained, and/or repaired by Liberty.

OBJECTION: This request is overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Liberty installs clean rooms in a host of different settings, including semiconductor manufacturing, aerospace electronics, laser and optic industries, microelectronic facilities, paint rooms, pharmaceuticals industries, research facilities. The specifications for a clean room vary based upon the work to be performed in the room. Notwithstanding this objection, Liberty has identified certifications related to NECP/Ameridose.

15. All documents related to complaints from Liberty's customers regarding any cleanroom it designed, constructed, installed, maintained, and/or repaired.

OBJECTION: See objection to production request 13. Notwithstanding this objection, after certification of the rooms, Liberty received no complaints from NECP or Ameridose aside from normal punch list items.

22. All documents, including correspondence, related to the products and equipment considered for the design, construction, installation, maintenance and/or repair of any NECP

cleanroom,, including documents related to the basis for using each product or piece of equipment.

OBJECTION: This request is overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. In addition, to the extent that it seeks documents related to products and equipment “considered”, it is vague.

25. All documents related to the instruments, monitors, machines, and other devices related to maintaining the sterility of any NECP cleanroom including warranties, instructions, service requirements, and maintenance information.

OBJECTION: Since Liberty provided none of the above-mentioned equipment, this request is vague. Further, it is incapable of meaningful response as “sterility” is assessed on a continuum. Different levels of sterility apply to different operations. More importantly, Liberty addresses particulates in the environment in a clean room, not sterility.

LIBERTY INDUSTRIES, INC.

By _____ /s/
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CERTIFICATION

This is to certify that on this 3rd day of July, 2013, a copy of the foregoing was filed electronically and served by mail on anyone unable to accept electronic filing. Notice of this filing will be sent by e-mail to all parties by operation of the Court's electronic filing system or by mail to anyone unable to accept electronic filing as indicated on the Notice of Electronic Filing. Parties may access this filing through the Court's CM/ECF System.

/s/

Nicole D. Dorman